

REQUEST FOR RECONSIDERATION
U.S. APPLN. NO. 09/998,429

application. The Examiner concludes that the prior art administration of the same ingredient in the same amount would inherently anticipate Applicant's claim 18.

Applicant's claim 18 is directed to a method of inducing IL-12 in a patient *in vivo* by orally administering AHCC to the patient. The Examiner's position appears to be that in his view Applicant's method of inducing IL-12 inherently occurs in the prior art of Ghoneum I and Ghoneum II.

Applicant must strenuously disagree with the Examiner's conclusion. For an inherency rejection to be proper, the claimed result must be shown to always occur in the prior art. If the administration of AHCC to a patient can be shown by Applicant to induce IL-12 at times, but not at other times, then the anticipation rejection based on inherency must be reconsidered and withdrawn.

As clearly shown in the present application, administration of AHCC does not inherently induce IL-12. In order to confirm this, the Examiner is respectfully referred to Examples 7 and 8 which begin at the middle of page 17 of the application. Note that continual administration of AHCC, combined with shark cartilage, over three months would not induce IL-12. On this basis, Applicants must respectfully submit that the Examiner's anticipation rejection is incorrect based on the legal meaning of "inherency". Accordingly, Applicants claims are not anticipated by Ghoneum I or Ghoneum II.

At the middle of page 3 of the Office Action, claim 19 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Ghoneum I or Ghoneum II in view of Fuji et al.

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The Examiner's position regarding Ghoneum I and Ghoneum II is discussed above. Fuji et al. is cited as teaching that components of fungal mycelia can be used as anticancer agents. The Examiner concludes that it would be obvious to the skilled artisan to use two known cancer therapies for their expected result.

First of all, the Examiner is respectfully requested to note that claim 19 is not directed to treating cancer, but to a method of inducing IL-12 in a patient by orally administering AHCC plus components of fungal mycelium. Since the Ghoneum I and Ghoneum II references do not teach inducing IL-12 in a patient by oral administration of AHCC, the rejection of claim 19 fails on that basis alone. Furthermore, Applicant advises that single use of PSK also does not necessarily result in IL-12 induction. Therefore, there will be no teaching or suggestion in the art that the combined use of fungal mycelium with AHCC would result in what has indeed been found by the inventor to be a synergistic induction of IL-12. Of course, the fact of a synergistic induction is not even needed for patentability of claim 19, since the Examiner has not cited any reference regarding use of fungal mycelium nor any reference regarding use of AHCC for induction of IL-12. Clearly, claim 19 is patentable.

In the last full paragraph on page 4 of the Office Action, claim 20 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Ghoneum I or Ghoneum II in view of Fuji et al., further in view of Sugawara et al.. Sugawara et al. is cited as disclosing components of hemolytic streptococci used as an anticancer agent. The Examiner therefore concludes that it would be obvious to combine it as a third ingredient with fungal mycelium and AHCC.

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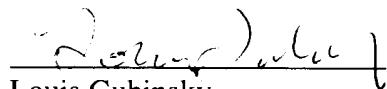
Clearly, claim 20 is allowable for the same reasons discussed above with respect to claim 19. Again, the Examiner has not cited any reference regarding the use of any of the three components of claim 20 for inducing IL-12 in a patient by oral administration thereof alone or in combination. Indeed, the present inventor has discovered a synergistic effect in inducing IL-12 which results from the combination as claimed. Claim 20 is patentable for all the reasons discussed above with respect to claims 18 and 19.

At the middle of page 6 of the Office Action, the Examiner rejects claims 18-20 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. 6,403,083. Although Applicant disagrees with this position, a terminal disclaimer is enclosed herewith to obviate this rejection.

In summary, Applicant submits that all claims should be in condition for allowance at this time. If any minor points remain prior to notice of allowance, the Examiner is respectfully requested to contact the undersigned at the below listed phone number.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,


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